

§ 866.5230

Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

§ 866.5230 Colostrum immunological test system.

(a) *Identification*. A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

§ 866.5240 Complement components immunological test system.

(a) *Identification*. A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C_{1q}, C_{1r}, C_{1s}, C₂, C₃, C₄, C₅, C₆, C₇, C₈, and C₉, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) *Classification*. Class II (performance standards).

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988]

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§ 866.5250 Complement C₂ inhibitor (inactivator) immunological test system.

(a) *Identification*. A complement C₂ inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C₂ inhibitor (a plasma protein) in serum. Complement C₂ inhibitor occurs normally in plasma and blocks the action of the C₁ component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C₂ inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

(b) *Classification*. Class II (performance standards).

§ 866.5260 Complement C_{3b} inactivator immunological test system.

(a) *Identification*. A complement C_{3b} inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_{3b} inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C_{3b} inactivator aids in the diagnosis of inherited antibody dysfunction.

(b) *Classification*. Class II (performance standards).

§ 866.5270 C-reactive protein immunological test system.

(a) *Identification*. A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(b) *Classification*. Class II (performance standards).

§ 866.5320 Properdin factor B immunological test system.

(a) *Identification*. A properdin factor B immunological test system is a device that consists of the reagents used